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October 14, 2003

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October 14, 2003 — Date

Robert E. Hanson

Mail Stop Appeal Brief-Patents
Commissioner for Patents
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Alexandria, VA 22313-1450

Re: SN 09/606,808 "TRANSFORMABLE INBRED CORN LINE L1ZL5 AND METHODS FOR USE THEREOF" – James R. Larkins, et al.;
Our Ref.. DEKA:264; Client Ref. 34-63(51675)

Commissioner:

Enclosed for filing in the above-referenced patent application is:

1. An Appeal Brief (an original and two copies);

2. A copy of a check in the amount of $320.00 that shows previous payment of the required filing fee on April 7, 2003; and

3. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

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Respectfully submitted,

Robert E. Hanson
Reg. No. 42,628

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
James R. Larkins et al.

Serial No.: 09/606,808

Filed: June 28, 2000

For: TRANSFORMABLE INBRED CORN LINE LIZL5 AND METHODS FOR USE THEREOF

Group Art Unit: 1638

Examiner: Mehta, A.

Atty. Dkt. No.: DEKA:264/REH

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Date

Robert E. Hanson

BRIEF ON APPEAL

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Serial No.: 09/606,808	Examiner: Mehta, A.
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BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief. The fee for filing this Appeal Brief was filed with the first Appeal Brief mailed in the case on April 7, 2003. The filing of this Appeal Brief was necessitated by the withdrawal of the finality of the previous Final Office Action by the Examiner and subsequent filing of the Notice of Appeal on August 8, 2003. The date for filing the instant Brief is October 14, 2003, based on the receipt of the Notice of Appeal by the Patent and Trademark Office on August 11, 2003. No fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/DEKA:264. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

There are no related interferences or appeals.

III. STATUS OF THE CLAIMS

Claims 1-39 were filed with the original application. Claims 1, 4, 7, 8, 10, 13, 18, 19 and 29 were amended in the Response to Office Action mailed in the case on January 2, 2002. Claims 9, 12, 19, 23 and 24 were amended in the Response to the Second Office Action mailed in the case on September 20, 2002 and the amendments subsequently entered. No claims have been canceled. Claims 1-39 were pending at the time of the Final Office Action and the Fourth Office Action mailed July 16, 2003. Claims 1 and 4-6 were allowed in the Fourth Office Action and claims 2, 3, and 7-39 were rejected. The current Appeal is of the rejection of claims 2, 3 and 7-39 in the Fourth Office Action. A copy of the appealed claims is attached hereto as Appendix 1 and a copy of the pending claims is attached as Appendix 2.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Final Office Action or the Fourth Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated LIZL5 and seeds or populations of seed thereof. Specification at page 5, lines 8-22. The invention also relates to single locus converted plants of LIZL5. Specification at page 6, lines 8-21. The invention further relates to methods for breeding LIZL5 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 6 to page 8, line 2. The invention still further relates to methods of transforming corn plant LIZL5 and the plants made thereby. Specification at page 9, lines 3-17.

VI. ISSUE ON APPEAL

(A) Are claims 2, 3 and 7-39 properly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention?

(B) Are claims 22-28 and 37-39 properly rejected under 35 U.S.C. §112, first paragraph, as not being supported by an adequate written description in the specification?

(C) Are claims 25-39 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled?

VII. GROUPING OF THE CLAIMS

The claims have been rejected for an alleged indefiniteness, lack of written description and enablement. Each of the appealed claims are directed to separate or progressively narrow embodiments of the invention. Different issues are thus raised for each of the claims under written description and enablement. The claims therefore stand or fall separately for purposes of the instant appeal.

VIII. SUMMARY OF THE ARGUMENT

Despite having already issued a Final Office Action and an Appeal Brief having been filed in the case, the Examiner withdrew the finality of the previous Office Action and issued fifteen new indefiniteness rejections. The rejections are poorly reasoned and made without reference to the general principle that all that is necessary under the second paragraph of 35 U.S.C. § 112 is that one of skill in the art understand what is claimed in view of the specification. The claims fully satisfy this requirement and thus the rejections are without merit.

The claims have also been rejected as lacking an adequate written description. However, Appellants have fully described the claimed subject matter. Each of the claimed hybrid plants and seeds having inbred corn plant LIZL5 as one parent have as half of their genome the same genetic contribution from LIZL5, given that corn plant LIZL5 is inbred. These plants therefore share this structural characteristic. The shared structural characteristic is fully described in the specification by way of the detailed descriptions in the specification and the biological deposit of seed of LIZL5. Single locus conversions of LIZL5 and LIZL5 transformed with a transgene are also fully described in the specification by way of the description of LIZL5 and added traits.

The Examiner has rejected the claims as allegedly not being enabled for production of single locus conversions and transformation of LIZL5. The rejection ignores working examples in the specification describing the production of exemplary single locus converted plants. The techniques are applicable to any transgene, all that is required is genetic transformation and/or multiple generations of backcrossing. The specification describes this and other techniques in great detail, fully enabling the claimed subject matter. The Examiner has nonetheless issued the rejection based solely on references having no applicability to maize. The rejection has also been made for an alleged failure to disclose "all" transgenes that could possibly be used.

However, this is not required for enablement. Appellants have disclosed more than a representative number of transgenes. The claims are thus fully enabled.

IX. ARGUMENT

A. The Rejections Under 35 U.S.C. §112, Second Paragraph Are Improper

1. Rejection of claim 2

The Action rejects claim 2 taking the position that "further defined as an essentially homogeneous population of inbred corn seed" is unclear as allegedly broadening the scope of the claim from which it depends. Appellants fail to understand the rejection. The independent claim 1, from which claim 2 depends, is directed to corn seed of the corn plant LIZL5. The current claim further narrows this by reciting a population of the seed in claim 1. This constitutes a further limitation of claim 1 as claim 1 does not require a population. There is therefore no basis to allege that claim 2 broadens the claim from which it depends. Instead, the converse is true.

With regard to the definition of "population," this term has a well known meaning in the art and thus the use of the term in the claims is not indefinite. Provided herewith as evidence of the well known meaning of "population" is a copy of the definition for the term from the on-line version of the Merriam-Webster™ dictionary. **Exhibit A**. Claims must be given their plain meaning and limitations from the specification are not read into a claim. The term is therefore fully definite and reversal of the rejection is respectfully requested.

2. Rejection of claims 3

Claim 3 is rejected for use of the term "further defined as essentially free from hybrid seed" as broadening the claim from which it depends. However, again, it is noted that the claim further defines the claim from which it depends by requiring that the seed be free of hybrid seed.

The limitation is not found in the independent claims. As such the claim is in proper dependent form. Reversal of the rejection is therefore respectfully requested.

3. Rejection of claim 7

Claim 7 has been rejected for the recitation of "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety LIZL5." The Examiner states that further modification with "essentially homogeneous" renders the claim indefinite because LIZL5 seed can only produce LIZL5 seeds. However, Appellants note that a population need not be essentially homogeneous, whether a population of plants or seeds. The relevant definition of "homogeneous" from the on-line version of the Merriam-Webster™ dictionary is "of uniform structure or composition throughout." **Exhibit B**. A population of plants grown from the seed of corn variety LIZL5 need not be of uniform structure and composition throughout. For example, the plants may vary in size, maturity or other characteristics due to environmental or other conditions, but still constitute a population of corn plants produced by growing the seed of corn variety LIZL5. As such, "essentially homogeneous" further defines the scope of the claim and the term as it is used is not indefinite. Reversal of the rejection is thus respectfully requested.

4. Rejection of claims 8, 10 and 13

The Examiner rejects claims 8, 10 and 13 for use of the term "capable of expressing." In particular, it is stated that it is unclear if the plant actually expresses the trait. Appellants note that the term "capable" is well know in the art and thus the claim is fully definite. Claim breadth is not indefiniteness. One of skill in the art would understand whether a corn plant is capable of expressing all of the traits of corn plant LIZL5 because Appellants have provided the corn plant LIZL5 by way of a biological deposit with the ATCC. One of skill in the art would therefore readily ascertain whether a plant is capable of expressing all of the traits of LIZL5 based on

direct comparisons. Because the standard is readily ascertainable, the use of the limitation in the claims is not indefinite. Reversal of the rejection is therefore respectfully requested.

5. Rejection of claim 9

The Action rejects claim 9 as allegedly broadening the scope of the claim from which it depends. Appellants note that the claim is a proper dependent claim that specifies an additional characteristic. Specifically, the claim adds "a cytoplasmic or nuclear gene conferring male sterility." This is an added element not in the independent claim. Claim 9 therefore: (1) contains a reference to the parent claim from which it depends, (2) contains a further limitation of the subject matter claimed in the main claim, and (3) incorporates all elements of the claim from which it depends. The claim is therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c) and is fully definite.

With regard to the Examiner's suggestion that the method by which the plant is made must be recited in the claim, Appellants note that a composition claim is a proper claim format and that there is no requirement that the claim be in product by process format. The means by which the plant is made are irrelevant to the definiteness of the claims, as the claims meet all requirements for a proper dependent composition claim, as set forth above.

Reversal of the rejection is therefore respectfully requested.

6. **Rejection of claim 11**

The Action rejects claim 11 taking the position that "derived from" in the recitation "wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks" is indefinite.

Appellant note that the term is fully definite based on the well known meaning of "derived." For example, the relevant dictionary definitions for "derived" from the on-line

version of the Merriam-Webster™ dictionary are "**1 a :** to take, receive, or obtain especially from a specified source **b :** to obtain (a chemical substance) actually or theoretically from a parent substance." **Exhibit C**. Both definitions indicate that the regenerable cells are obtained from the relevant compositions. Given the well known meaning, there is nothing indefinite in the recitation of the term in the claims. Reversal of the rejection is therefore respectfully requested.

7. Rejection of claim 12

The Action rejects claim 12 for use of the term "cells are in the form of protoplasts" because it is stated that protoplasts are not cells. However, Appellants note that the relevant dictionary definition from the on-line version of the Merriam-Webster™ dictionary for "protoplast" is "a plant cell that has had its cell wall removed." **Exhibit D**. A cell may therefore be a protoplast, although its cell wall has been removed. In view of this, the recitation of "cells are in the form of protoplasts" is not indefinite. Reversal of the rejection is therefore respectfully requested.

8. Rejection of claims 14 and 17

The Action states that "in accordance with" renders the claim indefinite because the meaning of the term is not exactly clear. In response, Appellants note that the term has a well known meaning in the art. As evidence of the meaning, Appellants have attached hereto the dictionary definition for "accordance" from the on-line version of the Merriam-Webster™ dictionary. (**Exhibit E**). As can be seen, the definition given is "agreement, conformity." The example sentence given in the definition is "in accordance with a rule" The term therefore has a well known meaning in the art and its use in the claim is not indefinite. Reversal of the rejection is therefore respectfully requested.

9. Rejection of claim 19

Claim 19 is rejected as being an improper dependent claim for allegedly not specifying how the process of claim 18 is further limited. This is incorrect. Claim 19 specifies that corn plant LIZL5 is crossed to a second, distinct inbred corn plant, whereas claim 18 is not so limited. In claim 18, LIZL5 may be crossed to a second plant that is not distinct from LIZL5 and is not inbred. In claim 19, LIZL5 must be crossed to a second, distinct inbred corn plant. Claim 19 therefore further narrows claim 18 and is in proper dependent form. The rejection of the Examiner is thus not understood. Reversal of the rejection is therefore respectfully requested.

10. Rejection of claim 25

The Action alleges that the recitation "further comprising a single locus conversion" renders the claim indefinite as broadening the scope of the claim from which it depends. Appellants note that the recited limitation is in addition to that of the main independent claim. The single locus is added to and modifies the plant recited in the independent claim. That is, claim 25: (1) contains a reference to the parent claim from which it depends, (2) contains a further limitation of the subject matter claimed in the main claim, and (3) incorporates all elements of the claim from which it depends. The claim is therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c). Reversal of the rejection is thus respectfully requested.

11. Rejection of claim 26

The Action rejects the claim for use of the term "wherein the single locus was stably inserted into a corn genome." It is alleged that the term renders the claim indefinite regarding whether the single locus was inserted into the genome of LIZL5 or that of a different plant.

In response, Appellants note that the single locus referred to in claim 26 may or may not have been directly inserted into the genome of the claimed plant. However, this does not render the claim indefinite. The single locus may have been inserted into a parent plant of variety

LIZL5 and self pollinated to produce the claimed plant. There is no need that the very plant claimed have been directly transformed because a single locus is stably transmitted through generations. The claim specifies that the single locus was stably inserted into a corn genome. Loci that are stably inserted into a corn genome are also stably inherited. Thus the single locus need not have been inserted into the genome of corn variety LIZL5. As such, the metes and bounds of the claim are clear and the claim is not indefinite. Reversal of the rejection is therefore respectfully requested.

12. Rejection of claim 28

The Action rejects claim 28 for use of the terms "yield enhancement," "improved nutritional quality," and "enhanced yield stability."

While relative, the terms must be read in the context of the claim in which they are found. The subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability. It is thus understood the enhancement of yield or yield stability and improvement in nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim would thus be fully understood by one of skill in the art and the use of the terms is not indefinite. Reversal of the rejection is therefore respectfully requested.

13. Rejection of claim 29 and 30

The Action rejects the claims alleging that "preselected DNA " is indefinite because it is not known what preselected means. In response, Appellants note that the term has a well known meaning in the art. This is evidenced by the definition from the on-line version of the Merriam-Webster™ dictionary for "preselected" as "to choose in advance usually on the basis of a particular criterion." **Exhibit F.** There is therefore nothing indefinite in specifying that the DNA has been chosen in advance based on a particular criteria. Contrary to the Examiner's

allegation, this does not apply to all DNA molecules. Not every DNA molecule need be selected in advance based on a given criteria. As such the use of the term is fully definite. Reversal of the rejection is therefore respectfully requested.

14. Rejection of claim 31

The Action alleges that "PEG mediated transformation of protoplasts" renders the claim indefinite because it does not further limit "contacting" the cells in claim 29.

Appellants admit to being baffled by the rejection. Claim 29 reads as follows:

> 29. A method of preparing a transgenic maize cell comprising:
> a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;
> b) contacting said cells with a pre-selected DNA; and
> c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

As can be seen, nowhere does the claim indicate that contacting in step b) comprises PEG mediated transformation, that any other transformation is used, or even that PEG is involved in any way. Claim 31 further defines step c) by reciting:

> 31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

Why the Examiner views PEG mediated transformation as not limiting is not understood. Specifying PEG mediated transformation as the transformation method in step b) of claim 29 further limits and defines claim 29. This constitutes a proper dependent claim limitation. Reversal of the rejection is therefore respectfully requested.

15. Rejection of claim 37

The Action rejects claim 37 for the use of the term "preparable." In response, Appellants note that the claim is in product by process format. The claim is defined by the process of claim

30. Product by process format is accepted and is not indefinite. The claim is therefore fully definite and reversal of the rejection is thus respectfully requested.

B. The Written Description Rejection of Claims 3, 14, 21 and 24-31 Has Been Improperly Maintained

1. Essentially homogeneous populations of seed of variety LIZL5 and populations of plants grown therefrom recited in claims 2 and 7 have been fully described

The Action rejects claims 2 and 7 as allegedly not describing essentially homogeneous populations of seed of corn variety LIZL5. As set forth above, a population is a group of individuals sharing a common characteristic, which need not be substantially homogeneous. The term "essentially homogeneous" properly modifies "population."

Claim 2 is directed to the inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed. As the claim is dependent and more narrow than claim 1, the rejection is improper under 37 C.F.R. 1.75(c), which requires that dependent claims be read as including all of the limitations of the claim from which they depend.

The rejection further is improper because the subject matter of claims 2 and 7 is literally described by the deposit of seed of LIZL5. Appellants have deposited a population of 2500 seeds with the ATCC. This provides literal support for claim 2. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). By growing the deposited seeds, an essentially homogenous population of plants according to claim 7 can also be produced. Therefore, literal description has also been provided for claim 7. Reversal of the rejection is thus respectfully requested.

2. **Hybrid plants have been fully described**

a) The claimed hybrid plants share the genetic complement of corn variety LIZL5

The Action has rejected claims directed to hybrid plants and seeds produced with corn plant LIZL5 as one parent as allegedly lacking written description. However, Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history at pages 24-25 of the specification, corn plant LIZL5 is an inbred corn plant. All of the claimed hybrid plants having LIZL5 as a parent will therefore contain a copy of the same genome as corn plant LIZL5. That is, because LIZL5 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant LIZL5, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant LIZL5 is described in the specification by way of the deposit of seed of corn plant LIZL5 with the ATCC. *See Enzo*, 296 F.3d at 1330. This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of

the members of the claimed genus of hybrids having LIZL5 as one parent share the structural feature of having the genetic complement of LIZL5. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

b) The shared characteristics of the claimed hybrid plants are readily identified and described in the specification

As set forth above, the claimed F1 hybrid plants having LIZL5 as one parent will share the same genetic complement received from LIZL5. This is readily identifiable by genetic marker analysis, as shown in Tables 6 and 8 of the specification. There shown is the SSR genetic marker profile of corn variety LIZL5, as well as an the exemplary hybrid plant designated 7026255 that was made using LIZL5 as one parent. As can be seen, hybrid corn plant 7026255 has the SSR genetic marker profile of LIZL5, and also includes the genetic markers from the second parent plant used to make the hybrid. The same will be true for any other hybrid plant having LIZL5 as one parent, save for an occasional difference at a locus due to spontaneous genetic rearrangements, which occur at statistically insignificant frequencies in essentially all organisms.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant LIZL5 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Appellants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals utility patents issued on hundreds of different corn

varieties. For example, a search of this website reveals more than 250 patents issued for corn varieties prior to the filing date of the current application, each of which were presumptively fully described in compliance with 35 U.S.C. §112, first paragraph. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety LIZL5 as one parent, and each of these would share the genetic complement of LIZL5.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As *any* second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Appellants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

The Action attempts to downplay the significance of the genetic marker data given in the specification by stating that some loci may be shared by other plants, that primer sequences are not described or that certain isozyme markers are not informative. However, no effort has been made to show that any substantial number of marker loci actually *are* shared by other plants. Further, Appellants do not claim such "other" plants, so this is irrelevant to written description. No basis has been provided to conclude that the claimed hybrid plants are not distinct and clearly identifiable by the genetic marker profile that has been set forth.

Regarding the availability of genetic markers, the service that was used to detect SSR markers is commercially available to the public. Further, SSR and any of the other genetic

marker systems that are well known to those of skill in the art may potentially be used, as is described on pages 56-57 of the specification. Regardless of whether SSR markers are used, the shared genetic complement of the claimed hybrid plants having corn variety LIZL5 as one parent distinguishes them. As the entire genome of corn variety LIZL5 has been described, at least, by way of the seed deposit that has been made, any polymorphic locus could be used including or in addition to the more than 60 SSR markers shown in Tables 6 and 8.

c) The Examiner's allegations that the expression of the genetic complement of corn variety LIZL5 is unpredictable are inapposite

The Examiner alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of variety LIZL5 because information is not provided regarding the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that Appellants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law further makes no distinctions regarding the manner in which applicants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Appellants have described the genetic complement of parent plant LIZL5 that will be comprised in the claimed hybrid plants. This has been achieved using the SSR and isozyme genetic marker profiles given in tables 5-8 of the specification. Indeed, Appellants describe the entire genetic complement of parent plant

LIZL5 by way of a seed deposit made with the ATCC. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d at 1330.

d) Appellants fully describe an exemplary hybrid made using inbred LIZL5

Further description of claimed hybrid plants is also provided in the specification by way of a detailed description of hybrid 7026255, which was produced with LIZL5 as one inbred parent. This plant is representative of hybrids produced using LIZL5 as one parent, each of which comprise the genetic complement of the parent corn plant as set forth above. Table 4 of the specification gives the performance characteristics for 7026255 and provides comparisons against other hybrid varieties. In Table 5, the morphological traits of 7026255 are given. The SSR profile for hybrid 7026255 is given in Table 8. This information, combined with the descriptions of LIZL5 in the specification and the shared structure among hybrids having corn plant LIZL5 as a parent, is more than adequate to describe the claimed subject matter.

3. **Single locus converted plants of corn variety LIZL5 and transformed plants of LIZL5 have been fully described**

The Examiner has maintained the rejection of claims directed to a single locus conversion of corn plant LIZL5 and transformed plants of LIZL5. In particular, the Examiner has alleged that: (1) the characteristics of the claimed single locus converted and transformed plants are unpredictable and/or not described, (2) the claims encompass genes that have yet to be discovered, and (3) the sequences and/or sources for the numerous examples of single locus traits disclosed in the application have not been described.

a) The claimed subject matter is not unpredictable

With regard to the first point made by the Examiner, it is noted that a "single locus converted (conversion) plant" is defined at page 21, lines 6-11 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". The Examiner's comments with regard to various allegedly unknown characteristics are thus outside the scope of the claims. With regard to the claimed subject matter, Appellants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant LIZL5 by way of the description and deposit of LIZL5 alone, not to mention other description provided. To hold otherwise would be to limit Appellants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)).

b) The Examiner has applied the written description requirement with respect to unclaimed subject matter

With respect to the Examiner's allegation that the claims encompass genes that have yet to be discovered, it is noted that Appellants ***do not claim undiscovered genes***. The claimed subject matter is the corn variety LIZL5 comprising a single locus conversion or genetic transformation of LIZL5. Any transgene may be introduced into corn variety LIZL5 to produce the claimed single locus conversion. The fact that a given gene could be isolated in the future

and introduced as a single locus conversion is irrelevant – the new gene is not claimed *per se*, a single locus conversion of corn plant LIZL5 is claimed. Under the reasoning of the Examiner, essentially any claim could be read to encompass subject matter yet to be invented and therefore not be described. A claim to a corn plant transformed with a *Bacillus thuringiensis* gene would be invalid because it would encompass corn varieties yet to be discovered. A claim to a given gene operably linked to a regulatory element would be invalid because as yet to be isolated regulatory elements would be encompassed. Nearly any biotechnological invention could be viewed this way applying the Examiner's reasoning. However, it is not any given single locus that is claimed, it is a corn plant of corn variety LIZL5 which comprises a single locus that has been claimed.

c) Appellants have disclosed numerous single locus traits and such traits were well known to those of skill in the art when the application was filed

The Examiner alleges that the traits recited in the application and referred to in Appellants previous response to office action have not been shown to have been known in the art. The Examiner has therefore invited Appellants to recite individual examples of single locus traits in the claims. However, the Examiner has ignored Appellants previous evidence submitted in the prior response to office action and also recited in the specification showing numerous single locus traits that were described.

Among just the examples in the specification recited with a publication reference or patent number are the following (see specification at pages 29-34): genes conferring male sterility (U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, incorporated by reference); male-sterility restorer genes (U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, incorporated by reference); a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060); and a

mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103).

The single locus traits are also described by way of PCT Application Publ. WO 95/06128, which was specifically incorporated by reference at page 29 of the specification. Examples of some of the single locus traits described in WO 95/06128, including any associated phenotype and publication reference given, are as follows:

the uidA gene from *E. Coli* encoding β-glucuronidase (GUS) (cells expressing *uidA* produce a blue color when given the appropriate substrate, Jefferson, R.A. 1987. *Plant Mol. Biol. Rep* 5: 387-405); the *bar* gene from *Streptomyces hygroscopicus* encoding phosphinothricin acetyltransferase (PAT) (cells expressing PAT are resistant to the herbicide Basta, White, J., Chang, S.-Y.P., Bibb, M.J., and Bibb, M.J. 1990. *Nucl. Ac. Research* 18: 1062); the *lux* gene from firefly encoding luciferase (cells expressing *lux* emit light under appropriate assay conditions, deWet, J.R., Wood, K.V., DeLuca, M., Helinski, D.R., Subramani, S. 1987. *Mol. Cell. Biol.* 7: 725-737); the *dhfr* gene from mouse encoding dihydrofolate reductase (DHFR) (cells expressing *dhfr* are resistant to methotrexate; Eichholtz, D.A., Rogers, S.G., Horsch, R.B., Klee, H.J., Hayford, M., Hoffman, N.L., Bradford, S.B., Fink, C., Flick, J., O'Connell, K.M., Frayley, R.T. 1987. *Somatic Cell Mol. Genet.* 13: 67-76); the *neo* gene from *E.Coli* encoding aminoglycoside phosphotransferase (APH) (cells expressing *neo* are resistant to the aminoglycoside antibiotics; Beck, E., Ludwig, G., Auerswald, E.A., Reiss, B., Schaller, H. 1982. *Gene* 19: 327-336); the *amp* gene from *E. Coli* encoding β-lactamase (cells expressing β-lactamase produce a chromogenic compound when given the appropriate substrate; Sutcliffe, J.G. 1978. *Proc. Nat. Acad. Sci.* USA 75: 3737-3741); the *xylE* gene from *Ps. putida* encoding catechol dihydroxygenase (cells expressing *xylE* produce a chromogenic compound when given the appropriate substrate; Zukowsky *et al.* 1983. *Proc. Nat. Acad. Sci.* USA 80: 1101-1105); the R,C1 and B genes from maize encode proteins that regulate anthocyanin biosynthesis in maize (Goff, S., Klein, T., Ruth, B., Fromm, M., Cone, K., Radicella, J., Chandler, V. 1990. *EMBO J.:* 2517-2522); the ALS gene from *Zea mays* encoding acetolactate synthase and mutated to confer resistance to sulfonylurea herbicides (cells expressing ALS are resistant to the herbicide; Gleen. Yang, L.Y., Gross, P.R., Chen, C.H., Lissis, M. 1992. *Plant Molecular Biology* 18: 1185-1187); the proteinase inhibitor II gene from potato and tomato (plants expressing the proteinase inhibitor II gene show increased resistance to insects; potato - Graham, J.S., Hall, G., Pearce, G., Ryan, C.A. 1986 *Mol. Cell. Biol.* 2: 1044-1051; tomato - Pearce, G., Strydom, D., Johnson, S., Ryan, C.A. 1991. *Science* 253: 895-898); the *Bt* gene from *Bacillus thuringensis* berliner 1715 encoding a protein that is toxic to insects (this gene is the coding sequence of *Bt* 884 modified in two regions for improved expression in plants; Vaeck, M., Reynaerts, A., Hofte, H., Jansens, S., DeBeuckeleer, M., Dean, C., Aeabeau, M., Van Montagu, M., and Leemans, J. 1987. *Nature* 328: 33-37); the *bxn* gene from *Klebsiella ozaeneae* encoding a nitrilase enzyme specific for the herbicide bromoxynil (cells expressing this gene are resistant to the herbicide bromoxynil; Stalker, D.m., McBride, K.E., and Malyj, L. *Science* 242: 419-422, 1988); the WGA-A gene encoding wheat germ agglutinin (expression of the WGA-A

gene confers resistance to insects; Smith, J.J., Raikhel, N.V. 1989. *Plant Mol. Biology* 13: 601-603); the *dapA* gene from *E. coli* encoding dihydrodipicolinate synthase (expression of this gene in plant cells produces increased levels of free lysine; Richaud, F., Richaud, C., Rafet, P. and Patte, J.C. 1986. *J. Bacteriol.* 166: 297-300); the *Z10* gene encoding a 10kd zein storage protein from maize (expression of this gene in cells alters the quantities of 10kD Zein in the cells; Kirihara, J.A., Hunsperger, J.P., Mahoney, W.C., and Messing, J. 1988. *Mol. Gen. Genet.* 211: 477-484); the Bt gene cloned from *Bacillus thuringensis* Kurstaki encoding a protein that is toxic to insects (the gene is the coding sequence of the cry IA(c) gene modified for improved expression in plants - plants expressing this gene are resistant to insects; Höfte, H. and Whiteley, H.R., 1989. *Microbiological Reviews.* 53: 242-255); the ALS gene from *Arabidopsis thaliana* encoding a sulfonylurea herbicide resistant acetolactate synthase enzyme (cells expressing this gene are resistant to the herbicide Gleen. Haughn, G.W., Smith, J., Mazur, B., and Somerville, C. 1988. *Mol. Gen. Genet.* 211: 266-271); the *dehl* gene from *Pseudomonas putida* encoding a dehalogenase enzyme (cells expressing this gene are resistant to the herbicide Dalapon; Buchanan-Wollaston, V., Snape, A., and Cannon, F. 1992. *Plant Cell Reports* 11: 627-631); the hygromycin phosphotransferase II gene from *E. coli* (expression of this gene in cells produces resistance to the antibiotic hygromycin. Waldron, C., Murphy, E.B., Roberts, J.L., Gustafson, G.D., Armour, S.L., and Malcolm, S.K. *Plant Molecular Biology* 5: 103-108, 1985); the *mtlD* gene cloned from *E. coli* (the gene encodes the enzyme mannitol-1-phosphate dehydrogenase; Lee and Saier, 1983. *J. of Bacteriol.* 153:685); the HVA-1 gene encoding a Late Embryogenesis Abundant (LEA) protein (the gene was isolated from barley; Dure, L., Crouch, M., Harada, J., Ho, T.-H. D. Mundy, J., Quatrano, R, Thomas, T, and Sung, R., *Plant Molecular Biology* 12: 475-486.

The foregoing represent just some of the single locus coding sequences that were known as of March 2, 1995, well before the filing date of the instant application. More than 25 regulatory elements were also described therein, as were numerous transformation vectors comprising combinations of these elements. Appellants could describe many more examples of single locus traits that were well known as of the filing date, and would be glad to do so should the Board find it useful. It thus goes without saying that single locus traits were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

Techniques for the introduction of single locus traits by genetic transformation were further well known to those of skill in the art. Some of the transformation methods for corn that were well known as of the filing date and cited in the specification include the following: electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No.

5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). Introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science, and it has not been alleged that this has not been described.

Appellants have therefore shown possession of the claimed single locus conversions. Both large numbers of single locus traits and the associated phenotypes were well known to those of skill in the art. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, LIZL5. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Appellants respectfully request reversal of the rejection.

4. Transformation of LIZL5 is fully described in the specification

Transformation of LIZL5 is fully described in the specification by way of the working examples and description of numerous well known transformation techniques. For example, Section XII of the specification describes the creation of transgenic plants and cells from LIZL5 using microprojectile bombardments as well as *Agrobacterium*-mediated bombardment.

Section XI of the specification described numerous transformation techniques that were well known in the art including: electroporation transformation (Bates, 1994; Lazzeri, 1995); protoplast transformation Bhattacharjee *et al.*, (1997); microprojectile bombardment (U.S. Patent No. 5,489,520; U.S. Patent No. 5,538,880; and U.S. Patent 6,025,545); *Agrobacterium*-mediated

transfer (Fraley *et al.*, (1985), Rogers *et al.*, (1987) and U.S. Patent No. 5,563,055); calcium phosphate precipitation, polyethylene glycol treatment, electroporation, and combinations of these treatments (*e.g.*, Potrykus *et al.*, 1985; Lorz *et al.*, 1985; Omirulleh *et al.*, 1993; Fromm *et al.*, 1986; Uchimiya *et al.*, 1986; Callis *et al.*, 1987; Marcotte *et al.*, 1988); direct uptake transformation (Omirulleh *et al.*, 1993); and silicon carbide fiber-mediated transformation (Kaeppler, 1990; Kaeppler *et al.*, 1992; U.S. Patent No. 5,563,055; PCT Application WO 95/06128; Thompson, 1995; Nagatani, 1997). In view of these methods and the working examples it cannot reasonably be claimed that Appellants were not in possession of transforming corn plant LIZL5. Reversal of the rejection is thus respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

The Action rejects claims 25-39 under 35 U.S.C. §112, first paragraph as allegedly not enabled.

1. The Examiner Misapplies the Law of Enablement by Requiring Disclosure of "All" Transgenes

The Action rejects the claims because it is stated that all transgenes have not been enabled. Specifically, it is stated that, while the specification is enabled when the transgene is known and the effect of expression is known, enablement allegedly is not provided for "all" transgenes.

Initially, Appellants initially note that the introduction of DNA into a cell occurs without regard to the nucleic acid transformed. Claims 29-39 require only a preselected DNA, not any given transgene. Thus the Examiners allegations are irrelevant with regard to these claims.

It is further noted that Appellants need not disclose every transgene ever known or that could ever possible be isolated. It is not the job of the specification to be a catalog of every

reagent known to man. Indeed the benefit of the specification would be lost if the public had to sort through thousands of pages listing various transgenes, not to mention every other ingredient or reagent that could possibly be used with the claims. The position taken by the Examiner in this regard is not reasonable. What is relevant here is that Appellants enable the scope of the claims with a representative number of transgenes with known phenotypes. Appellants have more than done so, as recited over several pages herein above. These represent well more than a representative sample of transgenes. Given this disclosure, there is no basis to reject the claim for not having disclosed "all" transgenes.

2. Single Locus conversions are fully enabled

The Examiner rejects claims directed to corn plants of variety LIZL5 comprising a single locus conversion. In an attempt to support the rejection, the Action cites several references alleged to show the difficulty of making male sterile or single locus converted plants. As noted before, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The Action nonetheless states that these references show effects such as linkage drag, epistasis and linkage disequilibrium that are not limited to just the plants exemplified in the cited references, and Applicant does not explain why these issues are not a concern for corn plants.

It appears that the Action has improperly placed the burden to show enablement on Appellants. The indication that the references concerning petunias, sugar beets and tomatoes applies to corn is made without any support. At the same time, the Action attempts to require Appellants to show why this is not true. Appellants respectfully note that it is the ***Office*** the bears the burden of supporting its rejections. This is underscored by the fact that Appellants describe the origin and breeding history of an exemplary single locus converted plant at pages 32-33. All of the steps described and carried out are the same as one would follow to prepare a conversion

of corn plant LIZL5. The Examiner has nonetheless ignored this example without providing a basis for doing so.

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA. Removal of the rejection is thus respectfully requested.

(3) Claims 29-36 Are Enabled in the Working Examples

Claims 29-36 concern a method of preparing a transgenic maize cell involving transformation of LIZL5. This is described in the working examples at Section XII of the specification. There described is the transformation of LIZL5 by *Agrobacterium*-mediated transformation and microprojectile bombardment transformation. The Examiner has not even addressed these examples.

Further, plant transformation in general was very well known to those of skill in the art at the time the application was filed. Plant transformation is not the point of novelty of this application, the corn variety LIZL5 is. This is illustrated by the numerous plant transformation techniques cited in the specification and listed above together with citations to publications in the art, including: electroporation transformation (Bates, 1994; Lazzeri, 1995); protoplast transformation Bhattacharjee *et al.*, (1997); microprojectile bombardment (U.S. Patent No.

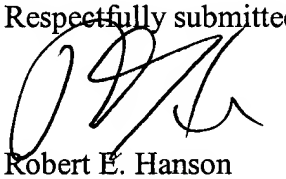
5,489,520; U.S. Patent No. 5,538,880; and U.S. Patent 6,025,545); *Agrobacterium*-mediated transfer (Fraley *et al.*, (1985), Rogers *et al.*, (1987) and U.S. Patent No. 5,563,055); calcium phosphate precipitation, polyethylene glycol treatment, electroporation, and combinations of these treatments (*e.g.*, Potrykus *et al.*, 1985; Lorz *et al.*, 1985; Omirulleh *et al.*, 1993; Fromm *et al.*, 1986; Uchimiya *et al.*, 1986; Callis *et al.*, 1987; Marcotte *et al.*, 1988); direct uptake transformation (Omirulleh *et al.*, 1993); and silicon carbide fiber-mediated transformation (Kaeppler, 1990; Kaeppler *et al.*, 1992; U.S. Patent No. 5,563,055; PCT Application WO 95/06128; Thompson, 1995; Nagatani, 1997).

The examples and known methods more than demonstrate the full enablement of the claims and no reason to the contrary has been provided by the Examiner. Reversal of the rejection is this requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



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Date: October 14, 2003

APPENDIX 1: APPEALED CLAIMS

2. The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.

3. The inbred corn seed of claim 1, further defined as essentially free from hybrid seed.

7. An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

8. A corn plant capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

9. The corn plant of claim 8, further comprising a cytoplasmic or nuclear gene conferring male sterility.

10. A tissue culture of regenerable cells of inbred corn plant LIZL5, wherein the tissue regenerates plants capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

11. The tissue culture of claim 10, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

12. The tissue culture of claim 11, wherein the regenerable cells are in the form of protoplasts or callus.

13. A corn plant regenerated from the tissue culture of claim 10, wherein said corn plant is capable of expressing all of the physiological and morphological characteristics of the inbred

corn plant designated LIZL5, a sample of the seed of said inbred corn plant designated LIZL5 having been deposited under ATCC Accession No. PTA-2192.

14. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

15. A corn seed comprising the inbred corn plant cell of claim 14.

16. A tissue culture comprising the inbred corn plant cell of claim 14.

17. The inbred corn plant of claim 8, comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

18. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein said first or second corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192, wherein seed is allowed to form.

19. The process of claim 18, further defined as a process of producing hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein said first inbred corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

20. The process of claim 19, wherein crossing comprises the steps of:

(a) planting in pollinating proximity seeds of said first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) emasculating the male flowers of said first or second inbred corn plant to produce an emasculated corn plant;

(d) allowing cross-pollination to occur between said first and second inbred corn plants; and

(e) harvesting seeds produced on said emasculated corn plant.

21. The process of claim 20, further comprising growing said harvested seed to produce a hybrid corn plant.

22. Hybrid corn seed produced by the process of claim 20.

23. A corn plant produced by the process of claim 21.

24. The corn plant of claim 23, wherein the plant is a first generation (F_1) hybrid corn plant.

25. The corn plant of claim 4, further comprising a single locus conversion.

26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.

27. The corn plant of claim 25, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

28. The corn plant of claim 25, wherein the locus confers a trait selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal, nematode or viral disease, yield enhancement, waxy starch, improved nutritional quality, enhanced yield stability, male sterility and restoration of male fertility.

29. A method of preparing a transgenic maize cell comprising:

a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;

b) contacting said cells with a pre-selected DNA; and

c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

30. The method of claim 29, further comprising the step of:

d) regenerating a fertile transgenic plant from said transgenic cell.

31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

32. The method of claim 31, wherein said contacting comprises use of microprojectile bombardment.

33. The method of claim 31, wherein said contacting comprises use of PEG mediated transformation of protoplasts.

34. The method of claim 31, wherein said contacting comprises use of electroporation.

35. The method of claim 31, wherein said contacting comprises use of silicon carbide fiber mediated transformation.

36. The method of claim 31, wherein said contacting comprises use of *Agrobacterium*-mediated transformation.

37. A fertile transgenic maize plant preparable by the process of claim 30.

38. A seed of the fertile transgenic maize plant of claim 37, wherein said seed comprises said pre-selected DNA.

39. A plant grown from the seed of claim 38, said plant comprising said pre-selected DNA.

APPENDIX 2: PENDING CLAIMS

1. Inbred corn seed of the corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

2. The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.

3. The inbred corn seed of claim 1, further defined as essentially free from hybrid seed.

4. An inbred corn plant produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

5. Pollen of the plant of claim 4.

6. An ovule of the plant of claim 4.

7. An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

8. A corn plant capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

9. The corn plant of claim 8, further comprising a cytoplasmic or nuclear gene conferring male sterility.

10. A tissue culture of regenerable cells of inbred corn plant LIZL5, wherein the tissue regenerates plants capable of expressing all the physiological and morphological characteristics

of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

11. The tissue culture of claim 10, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

12. The tissue culture of claim 11, wherein the regenerable cells are in the form of protoplasts or callus.

13. A corn plant regenerated from the tissue culture of claim 10, wherein said corn plant is capable of expressing all of the physiological and morphological characteristics of the inbred corn plant designated LIZL5, a sample of the seed of said inbred corn plant designated LIZL5 having been deposited under ATCC Accession No. PTA-2192.

14. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

15. A corn seed comprising the inbred corn plant cell of claim 14.

16. A tissue culture comprising the inbred corn plant cell of claim 14.

17. The inbred corn plant of claim 8, comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

18. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein said first or second corn plant is the inbred corn plant LIZL5, a

sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192, wherein seed is allowed to form.

19. The process of claim 18, further defined as a process of producing hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein said first inbred corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

20. The process of claim 19, wherein crossing comprises the steps of:

(a) planting in pollinating proximity seeds of said first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) emasculating the male flowers of said first or second inbred corn plant to produce an emasculated corn plant;

(d) allowing cross-pollination to occur between said first and second inbred corn plants; and

(e) harvesting seeds produced on said emasculated corn plant.

21. The process of claim 20, further comprising growing said harvested seed to produce a hybrid corn plant.

22. Hybrid corn seed produced by the process of claim 20.

23. A corn plant produced by the process of claim 21.

24. The corn plant of claim 23, wherein the plant is a first generation (F_1) hybrid corn plant.

25. The corn plant of claim 4, further comprising a single locus conversion.

26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.

27. The corn plant of claim 25, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

28. The corn plant of claim 25, wherein the locus confers a trait selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal, nematode or viral disease, yield enhancement, waxy starch, improved nutritional quality, enhanced yield stability, male sterility and restoration of male fertility.

29. A method of preparing a transgenic maize cell comprising:

a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;

b) contacting said cells with a pre-selected DNA; and

c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

30. The method of claim 29, further comprising the step of:

d) regenerating a fertile transgenic plant from said transgenic cell.

31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

32. The method of claim 31, wherein said contacting comprises use of microprojectile bombardment.

33. The method of claim 31, wherein said contacting comprises use of PEG mediated transformation of protoplasts.

34. The method of claim 31, wherein said contacting comprises use of electroporation.

35. The method of claim 31, wherein said contacting comprises use of silicon carbide fiber mediated transformation.

36. The method of claim 31, wherein said contacting comprises use of *Agrobacterium*-mediated transformation.

37. A fertile transgenic maize plant preparable by the process of claim 30.

38. A seed of the fertile transgenic maize plant of claim 37, wherein said seed comprises said pre-selected DNA.

39. A plant grown from the seed of claim 38, said plant comprising said pre-selected DNA.

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Main Entry: **pop·u·la·tion**
Pronunciation: `"pä-py&-'lA-sh&n`
Function: *noun*
Etymology: Late Latin *population-, populatio,* from Latin *populus*
Date: 1612
1 a : the whole number of people or inhabitants in a country or region **b :** the total of individuals occupying an area or making up a whole **c :** the total of particles at a particular energy level -- used especially of atoms in a laser
2 : the act or process of populating
3 a : a body of persons or individuals having a quality or characteristic in common **b** (1) **:** the organisms inhabiting a particular locality (2) **:** a group of interbreeding organisms that represents the level of organization at which speciation begins
4 : a group of individual persons, objects, or items from which samples are taken for statistical measurement
- **pop·u·la·tion·al** `/-shn&l, -sh&-n&l/` *adjective*

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One entry found for **homogeneous**.

Main Entry: **ho·mo·ge·neous**
Pronunciation: `-'jE-nE-&s, -ny&s`
Function: *adjective*
Etymology: Medieval Latin *homogeneus, homogenus,* from Greek *homogenEs,* from *hom-* + *genos* kind -- more at KIN
Date: 1641
1 : of the same or a similar kind or nature
2 : of uniform structure or composition throughout <a culturally *homogeneous* neighborhood>
3 : having the property that if each variable is replaced by a constant times that variable the constant can be factored out **:** having each term of the same degree if all variables are considered <a *homogeneous* equation>
- **ho·mo·ge·neous·ly** *adverb*
- **ho·mo·ge·neous·ness** *noun*

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One entry found for **derive**.

Main Entry: **de·rive**
Pronunciation: `di-'rIv, dE-`
Function: *verb*
Inflected Form(s): **de·rived**; **de·riv·ing**
Etymology: Middle English, from Middle French *deriver,* from Latin *derivare,* literally, to draw off (water), from *de-* + *rivus* stream -- more at RUN
Date: 14th century
transitive senses
1 a : to take, receive, or obtain especially from a specified source
b : to obtain (a chemical substance) actually or theoretically from a parent substance
2 : INFER, DEDUCE
3 *archaic* **:** BRING
4 : to trace the derivation of
intransitive senses **:** to have or take origin **:** come as a derivative
synonym see SPRING
- de·riv·er *noun*

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One entry found for **protoplast**.

Main Entry: **pro·to·plast**
Pronunciation: 'prO-t&-"plast
Function: *noun*
Etymology: Middle French *protoplaste,* from Late Latin *protoplastus* first human, from Greek *prOtoplastos* first formed, from *prOt-* prot- + *plastos* formed, from *plassein* to mold -- more at PLASTER
Date: 1532
1 : one that is formed first **:** PROTOTYPE
2 : a plant cell that has had its cell wall removed; *also* **:** the nucleus, cytoplasm, and plasma membrane of a cell as distinguished from inert walls and inclusions

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One entry found for **accordance**.

Main Entry: **ac·cor·dance**
Pronunciation: `&-'kor-d&n(t)s`
Function: *noun*
Date: 14th century
1 : AGREEMENT, CONFORMITY <in *accordance* with a rule>
2 : the act of granting

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One entry found for **preselect**.

Main Entry: **pre·se·lect**
Pronunciation: `"prE-s&-'lekt`
Function: *transitive verb*
Date: circa 1859
: to choose in advance usually on the basis of a particular criterion
- **pre·se·lec·tion** /`-'lek-sh&n`/ *noun*

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
James R. Larkins et al.

Serial No.: 09/606,808

Filed: June 28, 2000

For: TRANSFORMABLE INBRED CORN LINE LIZL5 AND METHODS FOR USE THEREOF

Group Art Unit: 1638

Examiner: Mehta, A.

Atty. Dkt. No.: DEKA:264/REH

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October 14, 2003
Date

Robert E. Hanson

BRIEF ON APPEAL

TABLE OF CONTENTS

Exhibit E: definition of "accordance" from the on-line version of the Merriam-Webster™ dictionary

Exhibit F: definition of "preselected" from the on-line version of the Merriam-Webster™ dictionary

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BRIEF ON APPEAL

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Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief. The fee for filing this Appeal Brief was filed with the first Appeal Brief mailed in the case on April 7, 2003. The filing of this Appeal Brief was necessitated by the withdrawal of the finality of the previous Final Office Action by the Examiner and subsequent filing of the Notice of Appeal on August 8, 2003. The date for filing the instant Brief is October 14, 2003, based on the receipt of the Notice of Appeal by the Patent and Trademark Office on August 11, 2003. No fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/DEKA:264. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

There are no related interferences or appeals.

III. STATUS OF THE CLAIMS

Claims 1-39 were filed with the original application. Claims 1, 4, 7, 8, 10, 13, 18, 19 and 29 were amended in the Response to Office Action mailed in the case on January 2, 2002. Claims 9, 12, 19, 23 and 24 were amended in the Response to the Second Office Action mailed in the case on September 20, 2002 and the amendments subsequently entered. No claims have been canceled. Claims 1-39 were pending at the time of the Final Office Action and the Fourth Office Action mailed July 16, 2003. Claims 1 and 4-6 were allowed in the Fourth Office Action and claims 2, 3, and 7-39 were rejected. The current Appeal is of the rejection of claims 2, 3 and 7-39 in the Fourth Office Action. A copy of the appealed claims is attached hereto as Appendix 1 and a copy of the pending claims is attached as Appendix 2.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Final Office Action or the Fourth Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated LIZL5 and seeds or populations of seed thereof. Specification at page 5, lines 8-22. The invention also relates to single locus converted plants of LIZL5. Specification at page 6, lines 8-21. The invention further relates to methods for breeding LIZL5 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 6 to page 8, line 2. The invention still further relates to methods of transforming corn plant LIZL5 and the plants made thereby. Specification at page 9, lines 3-17.

VI. ISSUE ON APPEAL

(A) Are claims 2, 3 and 7-39 properly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention?

(B) Are claims 22-28 and 37-39 properly rejected under 35 U.S.C. §112, first paragraph, as not being supported by an adequate written description in the specification?

(C) Are claims 25-39 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled?

VII. GROUPING OF THE CLAIMS

The claims have been rejected for an alleged indefiniteness, lack of written description and enablement. Each of the appealed claims are directed to separate or progressively narrow embodiments of the invention. Different issues are thus raised for each of the claims under written description and enablement. The claims therefore stand or fall separately for purposes of the instant appeal.

VIII. SUMMARY OF THE ARGUMENT

Despite having already issued a Final Office Action and an Appeal Brief having been filed in the case, the Examiner withdrew the finality of the previous Office Action and issued fifteen new indefiniteness rejections. The rejections are poorly reasoned and made without reference to the general principle that all that is necessary under the second paragraph of 35 U.S.C. § 112 is that one of skill in the art understand what is claimed in view of the specification. The claims fully satisfy this requirement and thus the rejections are without merit.

The claims have also been rejected as lacking an adequate written description. However, Appellants have fully described the claimed subject matter. Each of the claimed hybrid plants and seeds having inbred corn plant LIZL5 as one parent have as half of their genome the same genetic contribution from LIZL5, given that corn plant LIZL5 is inbred. These plants therefore share this structural characteristic. The shared structural characteristic is fully described in the specification by way of the detailed descriptions in the specification and the biological deposit of seed of LIZL5. Single locus conversions of LIZL5 and LIZL5 transformed with a transgene are also fully described in the specification by way of the description of LIZL5 and added traits.

The Examiner has rejected the claims as allegedly not being enabled for production of single locus conversions and transformation of LIZL5. The rejection ignores working examples in the specification describing the production of exemplary single locus converted plants. The techniques are applicable to any transgene, all that is required is genetic transformation and/or multiple generations of backcrossing. The specification describes this and other techniques in great detail, fully enabling the claimed subject matter. The Examiner has nonetheless issued the rejection based solely on references having no applicability to maize. The rejection has also been made for an alleged failure to disclose "all" transgenes that could possibly be used.

However, this is not required for enablement. Appellants have disclosed more than a representative number of transgenes. The claims are thus fully enabled.

IX. ARGUMENT

A. The Rejections Under 35 U.S.C. §112, Second Paragraph Are Improper

1. Rejection of claim 2

The Action rejects claim 2 taking the position that "further defined as an essentially homogeneous population of inbred corn seed" is unclear as allegedly broadening the scope of the claim from which it depends. Appellants fail to understand the rejection. The independent claim 1, from which claim 2 depends, is directed to corn seed of the corn plant LIZL5. The current claim further narrows this by reciting a population of the seed in claim 1. This constitutes a further limitation of claim 1 as claim 1 does not require a population. There is therefore no basis to allege that claim 2 broadens the claim from which it depends. Instead, the converse is true.

With regard to the definition of "population," this term has a well known meaning in the art and thus the use of the term in the claims is not indefinite. Provided herewith as evidence of the well known meaning of "population" is a copy of the definition for the term from the on-line version of the Merriam-Webster™ dictionary. **Exhibit A.** Claims must be given their plain meaning and limitations from the specification are not read into a claim. The term is therefore fully definite and reversal of the rejection is respectfully requested.

2. Rejection of claims 3

Claim 3 is rejected for use of the term "further defined as essentially free from hybrid seed" as broadening the claim from which it depends. However, again, it is noted that the claim further defines the claim from which it depends by requiring that the seed be free of hybrid seed.

The limitation is not found in the independent claims. As such the claim is in proper dependent form. Reversal of the rejection is therefore respectfully requested.

3. Rejection of claim 7

Claim 7 has been rejected for the recitation of "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety LIZL5." The Examiner states that further modification with "essentially homogeneous" renders the claim indefinite because LIZL5 seed can only produce LIZL5 seeds. However, Appellants note that a population need not be essentially homogeneous, whether a population of plants or seeds. The relevant definition of "homogeneous" from the on-line version of the Merriam-Webster™ dictionary is "of uniform structure or composition throughout." **Exhibit B**. A population of plants grown from the seed of corn variety LIZL5 need not be of uniform structure and composition throughout. For example, the plants may vary in size, maturity or other characteristics due to environmental or other conditions, but still constitute a population of corn plants produced by growing the seed of corn variety LIZL5. As such, "essentially homogeneous" further defines the scope of the claim and the term as it is used is not indefinite. Reversal of the rejection is thus respectfully requested.

4. Rejection of claims 8, 10 and 13

The Examiner rejects claims 8, 10 and 13 for use of the term "capable of expressing." In particular, it is stated that it is unclear if the plant actually expresses the trait. Appellants note that the term "capable" is well know in the art and thus the claim is fully definite. Claim breadth is not indefiniteness. One of skill in the art would understand whether a corn plant is capable of expressing all of the traits of corn plant LIZL5 because Appellants have provided the corn plant LIZL5 by way of a biological deposit with the ATCC. One of skill in the art would therefore readily ascertain whether a plant is capable of expressing all of the traits of LIZL5 based on

direct comparisons. Because the standard is readily ascertainable, the use of the limitation in the claims is not indefinite. Reversal of the rejection is therefore respectfully requested.

5. Rejection of claim 9

The Action rejects claim 9 as allegedly broadening the scope of the claim from which it depends. Appellants note that the claim is a proper dependent claim that specifies an additional characteristic. Specifically, the claim adds "a cytoplasmic or nuclear gene conferring male sterility." This is an added element not in the independent claim. Claim 9 therefore: (1) contains a reference to the parent claim from which it depends, (2) contains a further limitation of the subject matter claimed in the main claim, and (3) incorporates all elements of the claim from which it depends. The claim is therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c) and is fully definite.

With regard to the Examiner's suggestion that the method by which the plant is made must be recited in the claim, Appellants note that a composition claim is a proper claim format and that there is no requirement that the claim be in product by process format. The means by which the plant is made are irrelevant to the definiteness of the claims, as the claims meet all requirements for a proper dependent composition claim, as set forth above.

Reversal of the rejection is therefore respectfully requested.

6. Rejection of claim 11

The Action rejects claim 11 taking the position that "derived from" in the recitation "wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks" is indefinite.

Appellant note that the term is fully definite based on the well known meaning of "derived." For example, the relevant dictionary definitions for "derived" from the on-line

version of the Merriam-Webster™ dictionary are "**1 a :** to take, receive, or obtain especially from a specified source **b :** to obtain (a chemical substance) actually or theoretically from a parent substance." **Exhibit C**. Both definitions indicate that the regenerable cells are obtained from the relevant compositions. Given the well known meaning, there is nothing indefinite in the recitation of the term in the claims. Reversal of the rejection is therefore respectfully requested.

7. Rejection of claim 12

The Action rejects claim 12 for use of the term "cells are in the form of protoplasts" because it is stated that protoplasts are not cells. However, Appellants note that the relevant dictionary definition from the on-line version of the Merriam-Webster™ dictionary for "protoplast" is "a plant cell that has had its cell wall removed." **Exhibit D**. A cell may therefore be a protoplast, although its cell wall has been removed. In view of this, the recitation of "cells are in the form of protoplasts" is not indefinite. Reversal of the rejection is therefore respectfully requested.

8. Rejection of claims 14 and 17

The Action states that "in accordance with" renders the claim indefinite because the meaning of the term is not exactly clear. In response, Appellants note that the term has a well known meaning in the art. As evidence of the meaning, Appellants have attached hereto the dictionary definition for "accordance" from the on-line version of the Merriam-Webster™ dictionary. **(Exhibit E)**. As can be seen, the definition given is "agreement, conformity." The example sentence given in the definition is "in accordance with a rule" The term therefore has a well known meaning in the art and its use in the claim is not indefinite. Reversal of the rejection is therefore respectfully requested.

9. Rejection of claim 19

Claim 19 is rejected as being an improper dependent claim for allegedly not specifying how the process of claim 18 is further limited. This is incorrect. Claim 19 specifies that corn plant LIZL5 is crossed to a second, distinct inbred corn plant, whereas claim 18 is not so limited. In claim 18, LIZL5 may be crossed to a second plant that is not distinct from LIZL5 and is not inbred. In claim 19, LIZL5 must be crossed to a second, distinct inbred corn plant. Claim 19 therefore further narrows claim 18 and is in proper dependent form. The rejection of the Examiner is thus not understood. Reversal of the rejection is therefore respectfully requested.

10. Rejection of claim 25

The Action alleges that the recitation "further comprising a single locus conversion" renders the claim indefinite as broadening the scope of the claim from which it depends. Appellants note that the recited limitation is in addition to that of the main independent claim. The single locus is added to and modifies the plant recited in the independent claim. That is, claim 25: (1) contains a reference to the parent claim from which it depends, (2) contains a further limitation of the subject matter claimed in the main claim, and (3) incorporates all elements of the claim from which it depends. The claim is therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c). Reversal of the rejection is thus respectfully requested.

11. Rejection of claim 26

The Action rejects the claim for use of the term "wherein the single locus was stably inserted into a corn genome." It is alleged that the term renders the claim indefinite regarding whether the single locus was inserted into the genome of LIZL5 or that of a different plant.

In response, Appellants note that the single locus referred to in claim 26 may or may not have been directly inserted into the genome of the claimed plant. However, this does not render the claim indefinite. The single locus may have been inserted into a parent plant of variety

LIZL5 and self pollinated to produce the claimed plant. There is no need that the very plant claimed have been directly transformed because a single locus is stably transmitted through generations. The claim specifies that the single locus was stably inserted into a corn genome. Loci that are stably inserted into a corn genome are also stably inherited. Thus the single locus need not have been inserted into the genome of corn variety LIZL5. As such, the metes and bounds of the claim are clear and the claim is not indefinite. Reversal of the rejection is therefore respectfully requested.

12. Rejection of claim 28

The Action rejects claim 28 for use of the terms "yield enhancement," "improved nutritional quality," and "enhanced yield stability."

While relative, the terms must be read in the context of the claim in which they are found. The subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability. It is thus understood the enhancement of yield or yield stability and improvement in nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim would thus be fully understood by one of skill in the art and the use of the terms is not indefinite. Reversal of the rejection is therefore respectfully requested.

13. Rejection of claim 29 and 30

The Action rejects the claims alleging that "preselected DNA " is indefinite because it is not known what preselected means. In response, Appellants note that the term has a well known meaning in the art. This is evidenced by the definition from the on-line version of the Merriam-Webster™ dictionary for "preselected" as "to choose in advance usually on the basis of a particular criterion." **Exhibit F.** There is therefore nothing indefinite in specifying that the DNA has been chosen in advance based on a particular criteria. Contrary to the Examiner's

allegation, this does not apply to all DNA molecules. Not every DNA molecule need be selected in advance based on a given criteria. As such the use of the term is fully definite. Reversal of the rejection is therefore respectfully requested.

14. Rejection of claim 31

The Action alleges that "PEG mediated transformation of protoplasts" renders the claim indefinite because it does not further limit "contacting" the cells in claim 29.

Appellants admit to being baffled by the rejection. Claim 29 reads as follows:

> 29. A method of preparing a transgenic maize cell comprising:
> a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;
> b) contacting said cells with a pre-selected DNA; and
> c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

As can be seen, nowhere does the claim indicate that contacting in step b) comprises PEG mediated transformation, that any other transformation is used, or even that PEG is involved in any way. Claim 31 further defines step c) by reciting:

> 31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

Why the Examiner views PEG mediated transformation as not limiting is not understood. Specifying PEG mediated transformation as the transformation method in step b) of claim 29 further limits and defines claim 29. This constitutes a proper dependent claim limitation. Reversal of the rejection is therefore respectfully requested.

15. Rejection of claim 37

The Action rejects claim 37 for the use of the term "preparable." In response, Appellants note that the claim is in product by process format. The claim is defined by the process of claim

30. Product by process format is accepted and is not indefinite. The claim is therefore fully definite and reversal of the rejection is thus respectfully requested.

B. The Written Description Rejection of Claims 3, 14, 21 and 24-31 Has Been Improperly Maintained

1. Essentially homogeneous populations of seed of variety LIZL5 and populations of plants grown therefrom recited in claims 2 and 7 have been fully described

The Action rejects claims 2 and 7 as allegedly not describing essentially homogeneous populations of seed of corn variety LIZL5. As set forth above, a population is a group of individuals sharing a common characteristic, which need not be substantially homogeneous. The term "essentially homogeneous" properly modifies "population."

Claim 2 is directed to the inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed. As the claim is dependent and more narrow than claim 1, the rejection is improper under 37 C.F.R. 1.75(c), which requires that dependent claims be read as including all of the limitations of the claim from which they depend.

The rejection further is improper because the subject matter of claims 2 and 7 is literally described by the deposit of seed of LIZL5. Appellants have deposited a population of 2500 seeds with the ATCC. This provides literal support for claim 2. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). By growing the deposited seeds, an essentially homogenous population of plants according to claim 7 can also be produced. Therefore, literal description has also been provided for claim 7. Reversal of the rejection is thus respectfully requested.

2. **Hybrid plants have been fully described**

a) The claimed hybrid plants share the genetic complement of corn variety LIZL5

The Action has rejected claims directed to hybrid plants and seeds produced with corn plant LIZL5 as one parent as allegedly lacking written description. However, Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history at pages 24-25 of the specification, corn plant LIZL5 is an inbred corn plant. All of the claimed hybrid plants having LIZL5 as a parent will therefore contain a copy of the same genome as corn plant LIZL5. That is, because LIZL5 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant LIZL5, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant LIZL5 is described in the specification by way of the deposit of seed of corn plant LIZL5 with the ATCC. *See Enzo*, 296 F.3d at 1330. This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of

the members of the claimed genus of hybrids having LIZL5 as one parent share the structural feature of having the genetic complement of LIZL5. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

b) The shared characteristics of the claimed hybrid plants are readily identified and described in the specification

As set forth above, the claimed F1 hybrid plants having LIZL5 as one parent will share the same genetic complement received from LIZL5. This is readily identifiable by genetic marker analysis, as shown in Tables 6 and 8 of the specification. There shown is the SSR genetic marker profile of corn variety LIZL5, as well as an the exemplary hybrid plant designated 7026255 that was made using LIZL5 as one parent. As can be seen, hybrid corn plant 7026255 has the SSR genetic marker profile of LIZL5, and also includes the genetic markers from the second parent plant used to make the hybrid. The same will be true for any other hybrid plant having LIZL5 as one parent, save for an occasional difference at a locus due to spontaneous genetic rearrangements, which occur at statistically insignificant frequencies in essentially all organisms.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant LIZL5 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Appellants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals utility patents issued on hundreds of different corn

varieties. For example, a search of this website reveals more than 250 patents issued for corn varieties prior to the filing date of the current application, each of which were presumptively fully described in compliance with 35 U.S.C. §112, first paragraph. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety LIZL5 as one parent, and each of these would share the genetic complement of LIZL5.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As *any* second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Appellants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

The Action attempts to downplay the significance of the genetic marker data given in the specification by stating that some loci may be shared by other plants, that primer sequences are not described or that certain isozyme markers are not informative. However, no effort has been made to show that any substantial number of marker loci actually *are* shared by other plants. Further, Appellants do not claim such "other" plants, so this is irrelevant to written description. No basis has been provided to conclude that the claimed hybrid plants are not distinct and clearly identifiable by the genetic marker profile that has been set forth.

Regarding the availability of genetic markers, the service that was used to detect SSR markers is commercially available to the public. Further, SSR and any of the other genetic

marker systems that are well known to those of skill in the art may potentially be used, as is described on pages 56-57 of the specification. Regardless of whether SSR markers are used, the shared genetic complement of the claimed hybrid plants having corn variety LIZL5 as one parent distinguishes them. As the entire genome of corn variety LIZL5 has been described, at least, by way of the seed deposit that has been made, any polymorphic locus could be used including or in addition to the more than 60 SSR markers shown in Tables 6 and 8.

c) The Examiner's allegations that the expression of the genetic complement of corn variety LIZL5 is unpredictable are inapposite

The Examiner alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of variety LIZL5 because information is not provided regarding the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that Appellants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law further makes no distinctions regarding the manner in which applicants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Appellants have described the genetic complement of parent plant LIZL5 that will be comprised in the claimed hybrid plants. This has been achieved using the SSR and isozyme genetic marker profiles given in tables 5-8 of the specification. Indeed, Appellants describe the entire genetic complement of parent plant

LIZL5 by way of a seed deposit made with the ATCC. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d at 1330.

d) Appellants fully describe an exemplary hybrid made using inbred LIZL5

Further description of claimed hybrid plants is also provided in the specification by way of a detailed description of hybrid 7026255, which was produced with LIZL5 as one inbred parent. This plant is representative of hybrids produced using LIZL5 as one parent, each of which comprise the genetic complement of the parent corn plant as set forth above. Table 4 of the specification gives the performance characteristics for 7026255 and provides comparisons against other hybrid varieties. In Table 5, the morphological traits of 7026255 are given. The SSR profile for hybrid 7026255 is given in Table 8. This information, combined with the descriptions of LIZL5 in the specification and the shared structure among hybrids having corn plant LIZL5 as a parent, is more than adequate to describe the claimed subject matter.

3. **Single locus converted plants of corn variety LIZL5 and transformed plants of LIZL5 have been fully described**

The Examiner has maintained the rejection of claims directed to a single locus conversion of corn plant LIZL5 and transformed plants of LIZL5. In particular, the Examiner has alleged that: (1) the characteristics of the claimed single locus converted and transformed plants are unpredictable and/or not described, (2) the claims encompass genes that have yet to be discovered, and (3) the sequences and/or sources for the numerous examples of single locus traits disclosed in the application have not been described.

a) The claimed subject matter is not unpredictable

With regard to the first point made by the Examiner, it is noted that a "single locus converted (conversion) plant" is defined at page 21, lines 6-11 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". The Examiner's comments with regard to various allegedly unknown characteristics are thus outside the scope of the claims. With regard to the claimed subject matter, Appellants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant LIZL5 by way of the description and deposit of LIZL5 alone, not to mention other description provided. To hold otherwise would be to limit Appellants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)).

b) The Examiner has applied the written description requirement with respect to unclaimed subject matter

With respect to the Examiner's allegation that the claims encompass genes that have yet to be discovered, it is noted that Appellants ***do not claim undiscovered genes***. The claimed subject matter is the corn variety LIZL5 comprising a single locus conversion or genetic transformation of LIZL5. Any transgene may be introduced into corn variety LIZL5 to produce the claimed single locus conversion. The fact that a given gene could be isolated in the future

and introduced as a single locus conversion is irrelevant – the new gene is not claimed *per se*, a single locus conversion of corn plant LIZL5 is claimed. Under the reasoning of the Examiner, essentially any claim could be read to encompass subject matter yet to be invented and therefore not be described. A claim to a corn plant transformed with a *Bacillus thuringiensis* gene would be invalid because it would encompass corn varieties yet to be discovered. A claim to a given gene operably linked to a regulatory element would be invalid because as yet to be isolated regulatory elements would be encompassed. Nearly any biotechnological invention could be viewed this way applying the Examiner's reasoning. However, it is not any given single locus that is claimed, it is a corn plant of corn variety LIZL5 which comprises a single locus that has been claimed.

c) Appellants have disclosed numerous single locus traits and such traits were well known to those of skill in the art when the application was filed

The Examiner alleges that the traits recited in the application and referred to in Appellants previous response to office action have not been shown to have been known in the art. The Examiner has therefore invited Appellants to recite individual examples of single locus traits in the claims. However, the Examiner has ignored Appellants previous evidence submitted in the prior response to office action and also recited in the specification showing numerous single locus traits that were described.

Among just the examples in the specification recited with a publication reference or patent number are the following (see specification at pages 29-34): genes conferring male sterility (U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, incorporated by reference); male-sterility restorer genes (U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, incorporated by reference); a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060); and a

mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103).

The single locus traits are also described by way of PCT Application Publ. WO 95/06128, which was specifically incorporated by reference at page 29 of the specification. Examples of some of the single locus traits described in WO 95/06128, including any associated phenotype and publication reference given, are as follows:

the uidA gene from *E. Coli* encoding β-glucuronidase (GUS) (cells expressing *uidA* produce a blue color when given the appropriate substrate, Jefferson, R.A. 1987. *Plant Mol. Biol. Rep* 5: 387-405); the *bar* gene from *Streptomyces hygroscopicus* encoding phosphinothricin acetyltransferase (PAT) (cells expressing PAT are resistant to the herbicide Basta, White, J., Chang, S.-Y.P., Bibb, M.J., and Bibb, M.J. 1990. *Nucl. Ac. Research* 18: 1062); the *lux* gene from firefly encoding luciferase (cells expressing *lux* emit light under appropriate assay conditions, deWet, J.R., Wood, K.V., DeLuca, M., Helinski, D.R., Subramani, S. 1987. *Mol. Cell. Biol.* 7: 725-737); the *dhfr* gene from mouse encoding dihydrofolate reductase (DHFR) (cells expressing *dhfr* are resistant to methotrexate; Eichholtz, D.A., Rogers, S.G., Horsch, R.B., Klee, H.J., Hayford, M., Hoffman, N.L., Bradford, S.B., Fink, C., Flick, J., O'Connell, K.M., Frayley, R.T. 1987. *Somatic Cell Mol. Genet.* 13: 67-76); the *neo* gene from *E.Coli* encoding aminoglycoside phosphotransferase (APH) (cells expressing *neo* are resistant to the aminoglycoside antibiotics; Beck, E., Ludwig, G., Auerswald, E.A., Reiss, B., Schaller, H. 1982. *Gene* 19: 327-336); the *amp* gene from *E. Coli* encoding β-lactamase (cells expressing β-lactamase produce a chromogenic compound when given the appropriate substrate; Sutcliffe, J.G. 1978. *Proc. Nat. Acad. Sci.* USA 75: 3737-3741); the *xylE* gene from *Ps. putida* encoding catechol dihydroxygenase (cells expressing *xylE* produce a chromogenic compound when given the appropriate substrate; Zukowsky *et al.* 1983. *Proc. Nat. Acad. Sci.* USA 80: 1101-1105); the R,C1 and B genes from maize encode proteins that regulate anthocyanin biosynthesis in maize (Goff, S., Klein, T., Ruth, B., Fromm, M., Cone, K., Radicella, J., Chandler, V. 1990. *EMBO J.:* 2517-2522); the ALS gene from *Zea mays* encoding acetolactate synthase and mutated to confer resistance to sulfonylurea herbicides (cells expressing ALS are resistant to the herbicide; Gleen. Yang, L.Y., Gross, P.R., Chen, C.H., Lissis, M. 1992. *Plant Molecular Biology* 18: 1185-1187); the proteinase inhibitor II gene from potato and tomato (plants expressing the proteinase inhibitor II gene show increased resistance to insects; potato - Graham, J.S., Hall, G., Pearce, G., Ryan, C.A. 1986 *Mol. Cell. Biol.* 2: 1044-1051; tomato - Pearce, G., Strydom, D., Johnson, S., Ryan, C.A. 1991. *Science* 253: 895-898); the *Bt* gene from *Bacillus thuringensis* berliner 1715 encoding a protein that is toxic to insects (this gene is the coding sequence of *Bt* 884 modified in two regions for improved expression in plants; Vaeck, M., Reynaerts, A., Hofte, H., Jansens, S., DeBeuckeleer, M., Dean, C., Aeabeau, M., Van Montagu, M., and Leemans, J. 1987. *Nature* 328: 33-37); the *bxn* gene from *Klebsiella ozaeneae* encoding a nitrilase enzyme specific for the herbicide bromoxynil (cells expressing this gene are resistant to the herbicide bromoxynil; Stalker, D.m., McBride, K.E., and Malyj, L. *Science* 242: 419-422, 1988); the WGA-A gene encoding wheat germ agglutinin (expression of the WGA-A

gene confers resistance to insects; Smith, J.J., Raikhel, N.V. 1989. *Plant Mol. Biology* 13: 601-603); the *dapA* gene from *E. coli* encoding dihydrodipicolinate synthase (expression of this gene in plant cells produces increased levels of free lysine; Richaud, F., Richaud, C., Rafet, P. and Patte, J.C. 1986. *J. Bacteriol.* 166: 297-300); the *Z10* gene encoding a 10kd zein storage protein from maize (expression of this gene in cells alters the quantities of 10kD Zein in the cells; Kirihara, J.A., Hunsperger, J.P., Mahoney, W.C., and Messing, J. 1988. *Mol. Gen. Genet.* 211: 477-484); the Bt gene cloned from *Bacillus thuringensis* Kurstaki encoding a protein that is toxic to insects (the gene is the coding sequence of the cry IA(c) gene modified for improved expression in plants - plants expressing this gene are resistant to insects; Höfte, H. and Whiteley, H.R., 1989. *Microbiological Reviews.* 53: 242-255); the ALS gene from *Arabidopsis thaliana* encoding a sulfonylurea herbicide resistant acetolactate synthase enzyme (cells expressing this gene are resistant to the herbicide Gleen. Haughn, G.W., Smith, J., Mazur, B., and Somerville, C. 1988. *Mol. Gen. Genet.* 211: 266-271); the *dehl* gene from *Pseudomonas putida* encoding a dehalogenase enzyme (cells expressing this gene are resistant to the herbicide Dalapon; Buchanan-Wollaston, V., Snape, A., and Cannon, F. 1992. *Plant Cell Reports* 11: 627-631); the hygromycin phosphotransferase II gene from *E. coli* (expression of this gene in cells produces resistance to the antibiotic hygromycin. Waldron, C., Murphy, E.B., Roberts, J.L., Gustafson, G.D., Armour, S.L., and Malcolm, S.K. *Plant Molecular Biology* 5: 103-108, 1985); the *mtlD* gene cloned from *E. coli* (the gene encodes the enzyme mannitol-1-phosphate dehydrogenase; Lee and Saier, 1983. *J. of Bacteriol.* 153:685); the HVA-1 gene encoding a Late Embryogenesis Abundant (LEA) protein (the gene was isolated from barley; Dure, L., Crouch, M., Harada, J., Ho, T.-H. D. Mundy, J., Quatrano, R, Thomas, T, and Sung, R., *Plant Molecular Biology* 12: 475-486.

The foregoing represent just some of the single locus coding sequences that were known as of March 2, 1995, well before the filing date of the instant application. More than 25 regulatory elements were also described therein, as were numerous transformation vectors comprising combinations of these elements. Appellants could describe many more examples of single locus traits that were well known as of the filing date, and would be glad to do so should the Board find it useful. It thus goes without saying that single locus traits were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

Techniques for the introduction of single locus traits by genetic transformation were further well known to those of skill in the art. Some of the transformation methods for corn that were well known as of the filing date and cited in the specification include the following: electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No.

5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). Introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science, and it has not been alleged that this has not been described.

Appellants have therefore shown possession of the claimed single locus conversions. Both large numbers of single locus traits and the associated phenotypes were well known to those of skill in the art. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, LIZL5. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Appellants respectfully request reversal of the rejection.

4. Transformation of LIZL5 is fully described in the specification

Transformation of LIZL5 is fully described in the specification by way of the working examples and description of numerous well known transformation techniques. For example, Section XII of the specification describes the creation of transgenic plants and cells from LIZL5 using microprojectile bombardments as well as *Agrobacterium*-mediated bombardment.

Section XI of the specification described numerous transformation techniques that were well known in the art including: electroporation transformation (Bates, 1994; Lazzeri, 1995); protoplast transformation Bhattacharjee *et al.*, (1997); microprojectile bombardment (U.S. Patent No. 5,489,520; U.S. Patent No. 5,538,880; and U.S. Patent 6,025,545); *Agrobacterium*-mediated

transfer (Fraley *et al.*, (1985), Rogers *et al.*, (1987) and U.S. Patent No. 5,563,055); calcium phosphate precipitation, polyethylene glycol treatment, electroporation, and combinations of these treatments (*e.g.*, Potrykus *et al.*, 1985; Lorz *et al.*, 1985; Omirulleh *et al.*, 1993; Fromm *et al.*, 1986; Uchimiya *et al.*, 1986; Callis *et al.*, 1987; Marcotte *et al.*, 1988); direct uptake transformation (Omirulleh *et al.*, 1993); and silicon carbide fiber-mediated transformation (Kaeppler, 1990; Kaeppler *et al.*, 1992; U.S. Patent No. 5,563,055; PCT Application WO 95/06128; Thompson, 1995; Nagatani, 1997). In view of these methods and the working examples it cannot reasonably be claimed that Appellants were not in possession of transforming corn plant LIZL5. Reversal of the rejection is thus respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

The Action rejects claims 25-39 under 35 U.S.C. §112, first paragraph as allegedly not enabled.

1. The Examiner Misapplies the Law of Enablement by Requiring Disclosure of "All" Transgenes

The Action rejects the claims because it is stated that all transgenes have not been enabled. Specifically, it is stated that, while the specification is enabled when the transgene is known and the effect of expression is known, enablement allegedly is not provided for "all" transgenes.

Initially, Appellants initially note that the introduction of DNA into a cell occurs without regard to the nucleic acid transformed. Claims 29-39 require only a preselected DNA, not any given transgene. Thus the Examiners allegations are irrelevant with regard to these claims.

It is further noted that Appellants need not disclose every transgene ever known or that could ever possible be isolated. It is not the job of the specification to be a catalog of every

reagent known to man. Indeed the benefit of the specification would be lost if the public had to sort through thousands of pages listing various transgenes, not to mention every other ingredient or reagent that could possibly be used with the claims. The position taken by the Examiner in this regard is not reasonable. What is relevant here is that Appellants enable the scope of the claims with a representative number of transgenes with known phenotypes. Appellants have more than done so, as recited over several pages herein above. These represent well more than a representative sample of transgenes. Given this disclosure, there is no basis to reject the claim for not having disclosed "all" transgenes.

2. Single Locus conversions are fully enabled

The Examiner rejects claims directed to corn plants of variety LIZL5 comprising a single locus conversion. In an attempt to support the rejection, the Action cites several references alleged to show the difficulty of making male sterile or single locus converted plants. As noted before, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The Action nonetheless states that these references show effects such as linkage drag, epistasis and linkage disequilibrium that are not limited to just the plants exemplified in the cited references, and Applicant does not explain why these issues are not a concern for corn plants.

It appears that the Action has improperly placed the burden to show enablement on Appellants. The indication that the references concerning petunias, sugar beets and tomatoes applies to corn is made without any support. At the same time, the Action attempts to require Appellants to show why this is not true. Appellants respectfully note that it is the ***Office*** the bears the burden of supporting its rejections. This is underscored by the fact that Appellants describe the origin and breeding history of an exemplary single locus converted plant at pages 32-33. All of the steps described and carried out are the same as one would follow to prepare a conversion

of corn plant LIZL5. The Examiner has nonetheless ignored this example without providing a basis for doing so.

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA. Removal of the rejection is thus respectfully requested.

(3) Claims 29-36 Are Enabled in the Working Examples

Claims 29-36 concern a method of preparing a transgenic maize cell involving transformation of LIZL5. This is described in the working examples at Section XII of the specification. There described is the transformation of LIZL5 by *Agrobacterium*-mediated transformation and microprojectile bombardment transformation. The Examiner has not even addressed these examples.

Further, plant transformation in general was very well known to those of skill in the art at the time the application was filed. Plant transformation is not the point of novelty of this application, the corn variety LIZL5 is. This is illustrated by the numerous plant transformation techniques cited in the specification and listed above together with citations to publications in the art, including: electroporation transformation (Bates, 1994; Lazzeri, 1995); protoplast transformation Bhattacharjee *et al.*, (1997); microprojectile bombardment (U.S. Patent No.

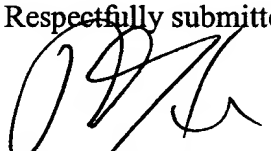
5,489,520; U.S. Patent No. 5,538,880; and U.S. Patent 6,025,545); *Agrobacterium*-mediated transfer (Fraley *et al.*, (1985), Rogers *et al.*, (1987) and U.S. Patent No. 5,563,055); calcium phosphate precipitation, polyethylene glycol treatment, electroporation, and combinations of these treatments (*e.g.*, Potrykus *et al.*, 1985; Lorz *et al.*, 1985; Omirulleh *et al.*, 1993; Fromm *et al.*, 1986; Uchimiya *et al.*, 1986; Callis *et al.*, 1987; Marcotte *et al.*, 1988); direct uptake transformation (Omirulleh *et al.*, 1993); and silicon carbide fiber-mediated transformation (Kaeppler, 1990; Kaeppler *et al.*, 1992; U.S. Patent No. 5,563,055; PCT Application WO 95/06128; Thompson, 1995; Nagatani, 1997).

The examples and known methods more than demonstrate the full enablement of the claims and no reason to the contrary has been provided by the Examiner. Reversal of the rejection is this requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



Robert E. Hanson
Reg. No. 42,628
Attorney for Appellants

FULBRIGHT & JAWORSKI L.L.P
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3085

Date: October 14, 2003

APPENDIX 1: APPEALED CLAIMS

2. The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.

3. The inbred corn seed of claim 1, further defined as essentially free from hybrid seed.

7. An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

8. A corn plant capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

9. The corn plant of claim 8, further comprising a cytoplasmic or nuclear gene conferring male sterility.

10. A tissue culture of regenerable cells of inbred corn plant LIZL5, wherein the tissue regenerates plants capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

11. The tissue culture of claim 10, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

12. The tissue culture of claim 11, wherein the regenerable cells are in the form of protoplasts or callus.

13. A corn plant regenerated from the tissue culture of claim 10, wherein said corn plant is capable of expressing all of the physiological and morphological characteristics of the inbred

corn plant designated LIZL5, a sample of the seed of said inbred corn plant designated LIZL5 having been deposited under ATCC Accession No. PTA-2192.

14. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

15. A corn seed comprising the inbred corn plant cell of claim 14.

16. A tissue culture comprising the inbred corn plant cell of claim 14.

17. The inbred corn plant of claim 8, comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

18. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein said first or second corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192, wherein seed is allowed to form.

19. The process of claim 18, further defined as a process of producing hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein said first inbred corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

20. The process of claim 19, wherein crossing comprises the steps of:

(a) planting in pollinating proximity seeds of said first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) emasculating the male flowers of said first or second inbred corn plant to produce an emasculated corn plant;

(d) allowing cross-pollination to occur between said first and second inbred corn plants; and

(e) harvesting seeds produced on said emasculated corn plant.

21. The process of claim 20, further comprising growing said harvested seed to produce a hybrid corn plant.

22. Hybrid corn seed produced by the process of claim 20.

23. A corn plant produced by the process of claim 21.

24. The corn plant of claim 23, wherein the plant is a first generation (F_1) hybrid corn plant.

25. The corn plant of claim 4, further comprising a single locus conversion.

26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.

27. The corn plant of claim 25, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

28. The corn plant of claim 25, wherein the locus confers a trait selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal, nematode or viral disease, yield enhancement, waxy starch, improved nutritional quality, enhanced yield stability, male sterility and restoration of male fertility.

29. A method of preparing a transgenic maize cell comprising:

a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;

b) contacting said cells with a pre-selected DNA; and

c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

30. The method of claim 29, further comprising the step of:

d) regenerating a fertile transgenic plant from said transgenic cell.

31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

32. The method of claim 31, wherein said contacting comprises use of microprojectile bombardment.

33. The method of claim 31, wherein said contacting comprises use of PEG mediated transformation of protoplasts.

34. The method of claim 31, wherein said contacting comprises use of electroporation.

35. The method of claim 31, wherein said contacting comprises use of silicon carbide fiber mediated transformation.

36. The method of claim 31, wherein said contacting comprises use of *Agrobacterium*-mediated transformation.

37. A fertile transgenic maize plant preparable by the process of claim 30.

38. A seed of the fertile transgenic maize plant of claim 37, wherein said seed comprises said pre-selected DNA.

39. A plant grown from the seed of claim 38, said plant comprising said pre-selected DNA.

APPENDIX 2: PENDING CLAIMS

1. Inbred corn seed of the corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

2. The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.

3. The inbred corn seed of claim 1, further defined as essentially free from hybrid seed.

4. An inbred corn plant produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

5. Pollen of the plant of claim 4.

6. An ovule of the plant of claim 4.

7. An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

8. A corn plant capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

9. The corn plant of claim 8, further comprising a cytoplasmic or nuclear gene conferring male sterility.

10. A tissue culture of regenerable cells of inbred corn plant LIZL5, wherein the tissue regenerates plants capable of expressing all the physiological and morphological characteristics

of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

11. The tissue culture of claim 10, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

12. The tissue culture of claim 11, wherein the regenerable cells are in the form of protoplasts or callus.

13. A corn plant regenerated from the tissue culture of claim 10, wherein said corn plant is capable of expressing all of the physiological and morphological characteristics of the inbred corn plant designated LIZL5, a sample of the seed of said inbred corn plant designated LIZL5 having been deposited under ATCC Accession No. PTA-2192.

14. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

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15. A corn seed comprising the inbred corn plant cell of claim 14.

16. A tissue culture comprising the inbred corn plant cell of claim 14.

17. The inbred corn plant of claim 8, comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

18. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein said first or second corn plant is the inbred corn plant LIZL5, a

sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192, wherein seed is allowed to form.

19. The process of claim 18, further defined as a process of producing hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein said first inbred corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

20. The process of claim 19, wherein crossing comprises the steps of:

(a) planting in pollinating proximity seeds of said first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) emasculating the male flowers of said first or second inbred corn plant to produce an emasculated corn plant;

(d) allowing cross-pollination to occur between said first and second inbred corn plants; and

(e) harvesting seeds produced on said emasculated corn plant.

21. The process of claim 20, further comprising growing said harvested seed to produce a hybrid corn plant.

22. Hybrid corn seed produced by the process of claim 20.

23. A corn plant produced by the process of claim 21.

24. The corn plant of claim 23, wherein the plant is a first generation (F_1) hybrid corn plant.

25. The corn plant of claim 4, further comprising a single locus conversion.

26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.

27. The corn plant of claim 25, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

28. The corn plant of claim 25, wherein the locus confers a trait selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal, nematode or viral disease, yield enhancement, waxy starch, improved nutritional quality, enhanced yield stability, male sterility and restoration of male fertility.

29. A method of preparing a transgenic maize cell comprising:

a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;

b) contacting said cells with a pre-selected DNA; and

c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

30. The method of claim 29, further comprising the step of:

d) regenerating a fertile transgenic plant from said transgenic cell.

31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

32. The method of claim 31, wherein said contacting comprises use of microprojectile bombardment.

33. The method of claim 31, wherein said contacting comprises use of PEG mediated transformation of protoplasts.

34. The method of claim 31, wherein said contacting comprises use of electroporation.

35. The method of claim 31, wherein said contacting comprises use of silicon carbide fiber mediated transformation.

36. The method of claim 31, wherein said contacting comprises use of *Agrobacterium*-mediated transformation.

37. A fertile transgenic maize plant preparable by the process of claim 30.

38. A seed of the fertile transgenic maize plant of claim 37, wherein said seed comprises said pre-selected DNA.

39. A plant grown from the seed of claim 38, said plant comprising said pre-selected DNA.

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Main Entry: **pop·u·la·tion**
Pronunciation: "pä-py&-'lA-sh&n
Function: *noun*
Etymology: Late Latin *population-, populatio,* from Latin *populus*
Date: 1612
1 a : the whole number of people or inhabitants in a country or region **b :** the total of individuals occupying an area or making up a whole **c :** the total of particles at a particular energy level -- used especially of atoms in a laser
2 : the act or process of populating
3 a : a body of persons or individuals having a quality or characteristic in common **b** (1) **:** the organisms inhabiting a particular locality (2) **:** a group of interbreeding organisms that represents the level of organization at which speciation begins
4 : a group of individual persons, objects, or items from which samples are taken for statistical measurement
- **pop·u·la·tion·al** /-shn&l, -sh&-n&l/ *adjective*

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\$^{&}$\ as **e** in kitten	\E\ as **ea** in easy	\oi\ as **oy** in boy
\&r\as **ur/er** in further	\g\ as **g** in go	\th\ as **th** in thin
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\A\ as **a** in ace	\I\ as **i** in ice	\ü\ as **oo** in loot
\ä\ as **o** in mop	\j\ as **j** in job	\u\ as **oo** in foot
\au\ as **ou** in out	\[ng]\ as **ng** in sing	\y\ as **y** in yet
\ch\ as **ch** in chin	\O\ as **o** in go	\zh\ as **si** in vision

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One entry found for **homogeneous**.

Main Entry: **ho·mo·ge·neous**
Pronunciation: `-'jE-nE-&s, -ny&s`
Function: *adjective*
Etymology: Medieval Latin *homogeneus, homogenus,* from Greek *homogenEs,* from *hom-* + *genos* kind -- more at KIN
Date: 1641
1 : of the same or a similar kind or nature
2 : of uniform structure or composition throughout <a culturally *homogeneous* neighborhood>
3 : having the property that if each variable is replaced by a constant times that variable the constant can be factored out : having each term of the same degree if all variables are considered <a *homogeneous* equation>
- **ho·mo·ge·neous·ly** *adverb*
- **ho·mo·ge·neous·ness** *noun*

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One entry found for **derive**.

Main Entry: **de·rive**
Pronunciation: `di-'rIv, dE-`
Function: *verb*
Inflected Form(s): **de·rived**; **de·riv·ing**
Etymology: Middle English, from Middle French *deriver,* from Latin *derivare,* literally, to draw off (water), from *de-* + *rivus* stream -- more at RUN
Date: 14th century
transitive senses
1 a : to take, receive, or obtain especially from a specified source
b : to obtain (a chemical substance) actually or theoretically from a parent substance
2 : INFER, DEDUCE
3 *archaic* **:** BRING
4 : to trace the derivation of
intransitive senses **:** to have or take origin **:** come as a derivative
synonym see SPRING
- de·riv·er *noun*

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One entry found for **protoplast**.

Main Entry: **pro·to·plast**
Pronunciation: `'prO-t&-"plast`
Function: *noun*
Etymology: Middle French *protoplaste,* from Late Latin *protoplastus* first human, from Greek *prOtoplastos* first formed, from *prOt-* prot- + *plastos* formed, from *plassein* to mold -- more at PLASTER
Date: 1532
1 : one that is formed first **:** PROTOTYPE
2 : a plant cell that has had its cell wall removed; *also* **:** the nucleus, cytoplasm, and plasma membrane of a cell as distinguished from inert walls and inclusions

Pronunciation Symbols

Click on the example word to hear it pronounced.

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One entry found for **accordance**.

Main Entry: **ac·cor·dance**
Pronunciation: `&-'kor-dᵊn(t)s`
Function: *noun*
Date: 14th century
1 : AGREEMENT, CONFORMITY <in *accordance* with a rule>
2 : the act of granting

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One entry found for **preselect**.

Main Entry: **pre·se·lect**
Pronunciation: `"prE-s&-'lekt`
Function: *transitive verb*
Date: circa 1859
: to choose in advance usually on the basis of a particular criterion
- **pre·se·lec·tion** /`-'lek-sh&n`/ *noun*

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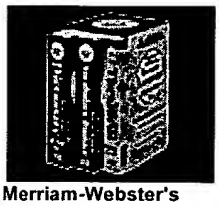
Pronunciation Symbols
Click on the example word to hear it pronounced.

\&\ as **a** and **u** in abut	\e\ as in bet	\o\ as **aw** in law
\^\ as in kitten	\E\ as **a** in easy	\oi\ as **oy** in boy
\&r\as **ur/er** in further	\g\ as **g** in go	\th\ as **th** in thin
\a\ as **a** in ash	\i\ as **i** in hit	\th\ as **th** in the
\A\ as **a** in ace	\I\ as **i** in ice	\ü\ as in loot
		\u\ as in foot



\ä\ as **o** in m__p
\au\ as **ou** in __ut
\ch\ as **ch** in **ch**in
\j\ as **j** in job
\[ng]\ as **ng** in sing
\O\ as **o** in go
\y\ as **y** in yet
\zh\ as **si** in vision

For more information see the Guide To Pronunciation.

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